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Acceptability and pilot efficacy trial of a web-based breast reconstruction decision support aid for women considering mastectomy

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Abstract

***Objective*: The study aim was to test the acceptability and preliminary efficacy of a novel interactive web-based breast reconstruction decision support aid (BRAID) for newly diagnosed breast cancer patients considering mastectomy.**

***Methods*: Fifty-five women considering mastectomy were randomly assigned to receive the BRAID versus the Cancer Support Community's Frankly Speaking About Cancer: Breast Reconstruction pamphlet. Participants completed measures of breast reconstruction (BR) knowledge, preparation to make a decision, decisional conflict, anxiety, and BR intentions before randomization and 2 weeks later.**

***Results*: In terms of acceptability, enrollment into the study was satisfactory, but the rate of return for follow-up surveys was lower among BRAID participants than pamphlet participants. Both interventions were evaluated favorably in terms of their value in facilitating the BR decision, and the majority of participants completing the follow-up reported viewing the materials. In terms of preliminary efficacy, both interventions resulted in significant increases in BR knowledge and completeness and satisfaction with preparation to make a BR decision, and both interventions resulted in a significant reduction in decision conflict. However, there were no differences between interventions.**

***Conclusion*: A widely available free pamphlet and a web-based customized decision aid were highly utilized. The pamphlet was as effective in educating women about BR and prepared women equally as well to make the BR decision as compared with a more costly, customized web-based decision support aid.**

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Background

Early-stage breast cancer is the most prevalent cancer among women in the USA [1]. Treatment varies depending on tumor characteristics, comorbidities, risk factors, and patient values and preferences. Surgical intervention entails breast-conserving surgery or mastectomy. Forty-one percent of patients undergo mastectomy [1]. Most women who undergo mastectomy are offered the option of breast reconstruction (BR). The major surgical procedures for reshaping the breast include implants or several different types of autologous tissue flap reconstruction. Although published rates vary [2,3], BR utilization has been on the rise since 2000 [4]. However, despite universal coverage for post-mastectomy BR, most women undergoing mastectomy do not undergo BR. Rates of BR range from 25% (population-based studies) [5,6] to approximately 50% (women treated in National Comprehensive Cancer Network participating centers [7]).

The BR choice is complicated by psychosocial and decisional factors. Women must make this decision in a compressed time frame, when they typically experience the heightened level of emotional distress that is associated with a new cancer diagnosis. Although most women select BR to improve their bodily appearance and maintain well-being, there is inconsistent evidence whether this outcome is achieved. Some studies report improved psychological outcomes among women who undergo BR compared with those who do not [8–12]. Other studies suggest no significant impact on well-being [13–15]. Additionally, there are mixed results regarding satisfaction with different BR types and timing of surgery [8,16–18].

Comprehensive decisional support, in terms of information about the benefits and risks of BR, is an important component in facilitating an informed decision about whether to have BR and what type of BR to choose. Usual care typically entails a discussion about interest in BR with the surgical oncologist, followed by consultation

with a plastic surgeon. However, research suggests that BR discussions with surgical oncologists may not occur or, if they do, often leave patients with unmet information and support needs [16,19]. Alderman and colleagues [16] proposed that uncertainty and perceived lack of being informed regarding BR options are primary reasons women do not choose BR. Women may not have a sufficient amount of time to make a fully informed decision [20,21]. Recent data suggest that values and attitudes impact decision-making [22]. A desire for breast symmetry, wanting to wake up from surgery with a breast in place, and the belief that it would be upsetting to look in the mirror and see a scar with no breast were rated as most frequent reasons to have BR.

To address the need for informed decision-making, we developed a web-based decision support aid. The development was guided by the Decision Support Framework (DSF), an evidence-based theoretical framework [23–25]. This framework indicates that individuals need information about the pros and cons of BR (decisional needs) and guidance in clarifying their values relevant to the BR decision (decision support). Decision support aids offer a useful resource for patients, complimenting and enhancing traditional methods of providing information and counseling, to facilitate a well-informed choice [25]. The DSF also guided assessment of knowledge, decisional conflict, and satisfaction. These measures are consistent with the DSF and decisional outcomes assessed in similar studies [26].

To date, two randomized trials examining BR decisional support tools have been published [27,28]. Heller and colleagues [27] tested a CD-ROM offered to women at the time of plastic surgery consultation. The CD-ROM improved knowledge, reduced anxiety, and increased post-operative satisfaction 1 month after surgery. A similar web-based aid showed comparable results [28]. The validity of these studies is limited. In one study, women seeking a second opinion were excluded, and half of participants dropped after randomization (the majority dropping because they wanted access to the CD-ROM [27]). Both studies [27,28] focused on women at the time of their plastic surgery consult, thereby selectively targeting women who are already considering BR and excluding those who may not have considered BR. Neither study assessed decision preparedness and conflict, possibly because women already considering BR were included.

The purpose of the present study was to test the acceptability and preliminary efficacy of a customized web-based breast reconstruction decision support aid (named BRAID) for newly diagnosed breast cancer patients considering mastectomy. The study advanced prior research in three ways. First, women were recruited at the time of their medical consultation where mastectomy was being considered or presented because of tumor size, and thus, women who may not have otherwise considered BR were included. This population may be less well-informed about BR options, expanding possible utility of the aid. Second, the BRAID was customized and offered some interactive features. An assessment and summary of participant's attitudes about BR facilitated more individualized decision-making based on attitudes as recommended by DSFs. Third, in order to provide a comparison with the best-available print information about BR and to minimize the potential for dropout due to lack of information (Heller et al., 2008 [27]), participants in the comparison arm of the study were given a free pamphlet that is published by the Cancer Support Community.

The present study had two aims. The first aim was to evaluate the acceptability of the BRAID. Acceptability was measured as study enrollment (acceptance rates), study retention (completion of follow-up measures), intervention use (BRAID and pamphlet), and intervention evaluation. The second aim was to evaluate the impact of the BRAID on BR knowledge, satisfaction with the preparation to make a decision, completeness of the preparation to make the decision, and decisional conflict. Secondary outcomes included anxiety, intention to have BR, decisions about BR, and reasons to have and not have BR. We conducted a pilot randomized clinical trial to provide preliminary data on these outcomes. The BRAID was compared against a widely-available informational pamphlet. We selected the most comprehensive print information available for patients on BR to provide the best-possible print comparison of the online BRAID. We proposed that participants receiving the BRAID would report greater increases in BR knowledge and preparedness to make a decision and greater declines in decisional conflict as compared with participants receiving the pamphlet. Because the BRAID was intended to improve preparedness rather than promote BR, we did not make a priori predictions regarding anxiety, BR intentions and decisions, or changes in reasons to have or not have BR.

Methods

Participants

The sample consisted of 55 female breast cancer patients recruited from outpatient clinics of surgical oncologists in four centers in the Northeastern USA (Rutgers Cancer Institute of New Jersey, Fox Chase Cancer Center, Cooper Cancer Institute, and Meridian Health Systems). Eligibility criteria were as follows: (1) female, (2) >18 years, (3) English speaking, (4) diagnosed with ductal carcinoma in situ (DCIS) or stage 1, 2, or 3a breast cancer, (5) considering mastectomy, but had not yet had the surgery, and (6) home Internet access or willingness to use the patient education center computer to access the web-based BRAID, if assigned to this condition.

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Procedures

Participants were identified by the attending surgeon and approached after the medical consultation where possible mastectomy was discussed. The surgeon provided a study overview and obtained permission for staff to follow-up with interested women. Participants signed an informed consent document approved by the Institutional Review Board at each site. After the consent and baseline survey were received, participants were randomized to BRAID or pamphlet conditions. Participants were assigned to condition after the baseline packets and consent forms were completed. To ensure that all of the sites followed the same randomization procedures, Fox Chase Cancer Center's Biostatistics and Bioinformatics Facility created a randomization scheme and hosted it on a web-enabled platform for each study site. The research staff was not blind to randomization. The BRAID group received written instructions for accessing the BRAID and a telephone support number. The pamphlet group received the pamphlet in the mail. Participants in both conditions received a follow-up survey 2 weeks after the baseline. A short evaluation was also collected on the telephone from BRAID participants at the 2-week time point. Data were collected between January 2013 and August 2014.

Interventions

Decision support aid: The BRAID was developed in three phases. First, a preliminary outline was constructed by the study team, which included four breast cancer surgeons (R. B., M. B., and E. S.), the reconstruction surgeon (N. T.), breast cancer oncologist (G. G.), the study PI (S. M.), and the team from Triad Interactive in a series of team meetings and discussions. A prototype was subsequently created by Triad Interactive, Inc. (Washington, DC, USA), a software company with experience in designing interactive web-based training and educational programs. The prototype was circulated to the study team for feedback. Comments were shared by team members on the website and discussed in several team meetings, with consensus guiding content and function modifications. Several iterations of the BRAID followed this procedure to refine content. Second, 11 women participated in in-depth interviews (conducted by S. M.) concerning their BR decision-making process and experiences (e.g., factors considered in the decision; the biggest reason to have/not have BR; information obtained from surgeon, oncologist, and plastic surgeon and how helpful it was; whether a plastic surgeon was consulted before making decision; information from the internet; and feelings about the decision made). Nine participants had chosen BR, and two had decided against BR. Videotaped interviews were viewed by the study team, and any unique additional information that was not already content in the content was added to the intervention content. The interviews were also video recorded for use in the video clip portion of the BRAID. Third, two women who participated in the interviews (both had undergone BR) reviewed the BRAID and provided feedback on content, graphics, and usability. They completed evaluations of the ease of use and content and re-reviewed the BRAID after the changes were made.

The BRAID is a menu-driven program organized into 10 modules. Modules are described in detail in Table 1. BRAID is self-paced and expected to take approximately 74 min to complete. After viewing the introductory tour, users encounter a home menu page that lists modules addressing an identified area of need for women considering BR. The values and attitudes module is interactive. The first screen asks the participant to indicate whether they have made a decision about BR, what the decision is, and what type of BR they prefer. The second to ninth screens present the participants' original answers to the values and attitudes questions, and they are offered the opportunity to change their answers. The 10th screen presents the reasons to have BR that the participant most strongly agreed with, along with the category (e.g., appearance concerns and partner concerns). The 11th screen presents the reasons not to have BR that the participant most strongly agreed with, along with the category. The 12th screen contained videos addressing concerns in each of the categories, and participants could view any or all of the videos.

Modules are voice narrated and include a variety of graphics (e.g., illustrations of reconstruction procedures). Women choose modules and video clips to view. Video clips of patient narratives are included in all modules. Users can record and print questions. Participants also received usual care, which consisted of a referral to a plastic surgeon if BR was being considered and a discussion with the treating surgeon.

Pamphlet intervention: A free 56-page Cancer Support Community pamphlet entitled Frankly Speaking about Cancer: Spotlight on Breast Reconstruction (https://orders.cancersupportcommunity.org) contains a description of considerations for BR ('does it matter that the reconstruction process involves multiple steps?'), a set of questions to ask the plastic surgeon (e.g., 'Will my breasts look relatively the same?'), information about types of breast surgery and BR, possible timing considerations for BR, reasons why women choose not to have BR, information about breast forms and prostheses, what to expect before and after BR surgery, how to cope with 'the new normal', and a summary table of BR options. The pamphlet contains similar educational information about BR options and a description of considerations. However, it does not contain the video clips of women discussing their experiences, does not contain an interactive assessment and clarification of patient values and attitudes about BR, does not contain photos of reconstructed breasts, and does not contain a timeline for reconstructive surgeries. Similar to

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Table I. Breast reconstruction decision support aid module content

Module	Description
Introductory tour	Orientation program that describes the BRDA and provides basic training in navigating it
BR overview	Outlines facts concerning reconstruction, including post-mastectomy options, timing of BR, criteria surgical oncologists considered when making a recommendation, and more
Implants	Offers information specific to implant reconstruction and presents elements considered when defining an ideal candidate for implant BR, saline versus silicone options, one-stage versus two-stage reconstruction, possible complications, pros and cons, and outcomes; patient photos are included as well as video clips of patient narratives
Abdominal tissue	Provides details about reconstruction procedures using abdominal tissue and presents factors considered when defining an ideal candidate, pedicled versus free TRAM flap techniques, possible complications, timeline, pros and cons, and outcomes; patient photos are included as well as video clips of patient narratives
Back tissue	Covers information about reconstruction using back tissue and presents features considered when defining an ideal candidate, latissimus dorsi with or without implant options, possible complications, timeline, and pros and cons; patient photos are included as well as video clips of patient narratives
No reconstruction	Explores why some women choose not to have reconstruction after mastectomy, touching on motivating factors, timeline, and prosthetic options; patient photos are presented as well as video clips of patient narratives
Nipple and areola reconstruction	Presents information concerning nipple reconstruction and areola tattooing and grafting options; patient photos are included as well as video clips of patient narratives
Women's stories	Contains video clips depicting personal narratives of women discussing what went into their decisions to have reconstruction or not; patients who elected reconstruction using implants, abdominal tissue, and back tissue are included as well as a patient who chose not to have reconstruction after mastectomy; users have the ability to filter the list of video thumbnails by selecting a number of options related to reconstruction facts and decision-making factors (e.g., emotional reactions to the process and family and partner input)
Your values and attitudes	Patients (to review) can change their answers to baseline survey questions regarding reconstruction values and attitudes; these consist of reasons to have (e.g., the desire for a normal breast shape) and not have BR (e.g., risks and complications); after answers, a summary of key values is generated that the patient can review, print, and/or email to themselves
Questions to ask	Allows patients to create a questions' list that can be printed or emailed

BRDA, breast reconstruction decision aid; BR, breast reconstruction; TRAM, transverse rectus abdominis myocutaneous.

the BRAID, women in the pamphlet condition also received usual care.

Acceptability measures

Acceptability was measured as study enrollment (acceptance rates), study retention (completion of follow-up measures), intervention utilization, and intervention evaluation. Intervention utilization was measured in the follow-up survey by asking whether the participant read (pamphlet) or logged into the website, whether they showed or discussed the information to family or friends, and whether they showed or discussed the information with their doctors (yes/no). For BRAID participants, data were extracted from the website on the amount of time each participant spent viewing the decision aid. Pamphlet utilization was also assessed by asking how much of the pamphlet they read.

The intervention evaluation consisted of a nine items rated on a 7-point Likert scale (1 = *not at all* to 7 = *extremely)* assessing whether the decision aid or pamphlet was balanced, informative, easy to understand, interesting, valid, valuable, appropriate in length, helpful in understanding the advantages and disadvantages of BR options, and helpful in arriving at a decision.

Efficacy measures

Baseline demographic and medical variables: Patients reported age, income, ethnicity, marital status, occupational status, insurance status, and education. Patients' stage of disease, date of diagnosis, and Eastern Cooperative Oncology Group (ECOG) performance status [29] were collected from study chart. ECOG was collected to evaluate whether patients with poorer performance status would be more likely to refuse the study. Additionally, we recorded whether or not the participant had seen a plastic surgeon for a BR consultation before completing the survey.

Knowledge about breast reconstruction: A 19-item knowledge survey was developed by the study's BR (N. T.). This measure included 11 face-valid true–false items assessing knowledge about procedures and risks and eight multiple choice items assessing knowledge about complications and BR types. A sample true–false item is 'After surgery, it may take as long as 1 to 2 years to completely heal.' A sample multiple choice item is 'Tissue flap procedures use tissue from which of the following areas of the body to rebuild the breast' (choices: tummy, back, thighs, buttocks, do not know, and all of the above). Knowledge scores were calculated as the percent correct. Internal consistency as estimated by coefficient alpha was 0.84 (baseline) and 0.65 (follow-up).

Satisfaction with the preparation for the breast reconstruction decision: A seven-item measure that assessed satisfaction with the preparation to make a decision was adapted from prior research on decisions regarding microsatellite instability testing [30]. A sample item is 'How satisfied are you with the amount of information you received thus far?' Items were rated on a 5-point scale (*not at all satisfied* to *extremely satisfied*). A scale item mean was calculated. Internal consistency for this scale

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as estimated by coefficient alpha was 0.93 (baseline) and 0.86 (follow-up).

Completeness of the preparation for the breast reconstruction decision: A 12-item completeness of preparation scale was adapted from prior research on decisions regarding microsatellite instability testing [30]. Items included 'I have been given a sufficient amount of information about the purpose of undergoing breast reconstruction surgery' and 'The information I received covered the main reasons some people choose not to have breast reconstruction.' Items were rated on a 4-point scale (1 = *strongly disagree*; 4 = *strongly agree*). A scale item mean was calculated. Internal consistency for this scale as estimated by coefficient alphas was 0.95 (baseline) and 0.86 (follow-up).

Decisional conflict: The Decisional Conflict Scale [31,32] is a 16-item measure used in studies evaluating decisional processes in medical settings [33]. Items are rated on a 5-point Likert scale (1 = *strongly agree* to 5 = *strongly disagree*). Higher scores indicate greater decisional conflict. Items were revised to reflect the BR decision (e.g., 'I am clear about how important the potential benefits of *breast reconstruction* are to me in this decision'). Internal consistency as estimated by coefficient alpha was 0.96 (baseline) and 0.94 (follow-up).

Anxiety: The state version of the State–Trait Anxiety Inventory [34] was used. This 21-item measure assesses anxiety symptoms (e.g., 'I am tense'). Items are rated on a 4-point Likert scale (1 = *almost never* to 4 = *almost always*). Participants rated how they presently feel. Internal consistency as estimated by coefficient alpha was 0.94 (baseline) and 0.94 (follow-up).

Reasons to have and not have breast reconstruction: A 25-item survey was developed using two methods. First, we loosely adapted six items from the breast cancer decision making measure [35], which examined women's choices of mastectomy versus breast-conserving surgery. The remaining items were based on a literature review. Revisions were made by breast cancer surgeons. Reasons included appearance, femininity, emotions, relationship influences and concerns, surgical risks, knowledge, and physician interaction. Two scales were formed: reasons to have BR (17 items) and reasons not to have BR scale (eight items). Items were rated on a 5-point scale (1 = *strongly disagree* to 5 = *strongly agree*). Internal consistency for the reasons to have BR scale as estimated by coefficient alpha was 0.84 (baseline) and 0.93 (follow-up). Internal consistency for the reasons to not have BR scale as estimated by coefficient alpha was 0.64 (baseline and follow-up).

Breast reconstruction intentions and decisions: Participants were asked whether they made a definite decision about BR (yes/no). Participants who had made a decision indicated what option they were most interested in pursuing (or not choosing BR). Participants who did not make a decision rated their intentions on a 7-point Likert scale (1 = *not at all interested* to 7 = *extremely interested*) and what option they were most interested in: having or not having BR.

Analytic approach

For the efficacy analysis, means and standard deviations were calculated for each outcome, stratified by time point (baseline or follow-up) and treatment arm (pamphlet or BRAID). Within treatment arm, we examined whether the outcome changed significantly from baseline to follow-up. Next, we examined whether the observed changes differed significantly across treatment arms. These analyses were intent on treating analyses, in that all subjects were included regardless of whether they participated, as intended, in the assigned treatment arm or not. For the primary analyses, assuming that data were missing at random, we used mixed linear models, with time point as an indicator variable (equal to 0 for baseline and equal to 1 at follow-up). For the analyses of changes within treatment arms, we conducted stratified analyses by treatment arm, with time point as the single predictor in the model. For analyses for the treatment effect, an indicator variable for treatment arm (equal to 0 for pamphlet and equal to 1 for BRAID) was added along with an interaction between treatment arm and time point. Significance of the latter term was used to assess the treatment effect. In all models, a random effect for subject was included in order to account for correlation between measures across time within individual. Missing data were handled using three approaches: assuming that missing data were missing at random, using multiple imputation to 'fill in' the missing data, and employing the last observation carried forward to 'fill in' the missing data.

Results

Participant characteristics

Demographic and medical characteristics of the sample are in Table 1 (Supplementary Information). Participants ranged in age from 31 to 73 years (M = 50.2) and were predominantly White (80%), non-Hispanic (90.9%), married (54.5%), well-educated (52.8% ≥college degree), and medically insured (96.4%). Approximately half were diagnosed with DCIS or stage I cancer. Demographic and medical information is also shown separately for the two study arms. No significant differences were noted between arms.

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Indicators of acceptability

Enrollment: This information is presented in the Consolidated Standards of Reporting Trials (CONSORT) diagram in Figure 1. Of the 104 patients screened for eligibility, 97 (93.6%) were eligible, and 55 (56.7%) agreed to participate and were randomized to the BRAID ($n=31$) or pamphlet intervention ($n=24$). Reasons for ineligibility included the following: did not speak/read English, $n=3$; stage 3b cancer, $n=2$; prophylactic surgery, $n=1$; and definitely decided upon lumpectomy, $n=1$.

Refusers ranged in age from 30 to 76 years (M=52.5) and were predominantly White (59.5%), non-Hispanic (92.9%), diagnosed with DCIS or stage 1 disease (50%), and ECOG performance status asymptomatic (92.9%). Over 61% of those who declined did not provide a reason. Among women providing a reason, the most common reason for refusal was lack of perceived benefit from participation (9.5%). Comparisons were made between the 55 participants and the 42 refusers with regard to available data (i.e., age, race, ethnicity, disease stage, ECOG status, and time since diagnosis). No statistically significant differences were observed.

Retention: Of the 55 participants, 43 returned the follow-up survey (78%). A greater percentage of pamphlet participants completed follow-up measures in comparison with that of BRAID participants (91.7% vs. 67.7%). The difference in follow-up completion rates between intervention arms was statistically significant, X^2 (2, $n=55$)=4.54, $p=0.033$. Of the 12 participants who did not complete the follow-up survey, one participant enrolled in the BRAID arm stated the material was too much to review, two participants reported they were too overwhelmed by the cancer treatment process to continue their participation, and eight patients were lost to follow-up.

Intervention utilization: All participants in the BRAID arm who completed the follow-up survey reported logging into the BRAID website at the follow-up. Calculations from the log-in tracking data collected from the BRAID website indicated that 24/31 (77.4%) of participants logged into the BRAID. Two participants stated it was too much material to review, two gave no reason for not logging in, one participant stated she did not realize she was supposed to log in, one participant dropped before the follow-up, and one person stated he or she logged in on the follow-up, but the program did not record a log in. Among the participants with program tracking of log ins, approximately 85% spent between 18 and 96 min in BRAID. The median amount of time was 91 min, and the average time spent in the BRAID was 99.5 min (SD=65.5, range=4 to 273 min). All but one (95%) of the participants in the pamphlet arm reported looking at the pamphlet. Sixteen of the 21 pamphlet participants reported reading the pamphlet at least once, two reported read most of it, and one reported glancing at it. When the three indicators of utilization were calculated as a total (did they use, show/discuss with family/friends, and show/discuss with doctors, range=1–3), results indicated that use of the intervention materials was higher among BRAID participants (M=2.19, SD=0.6) in comparison with pamphlet participants [(M=1.59, SD=0.85), t (37.79)=2.67, $p=0.011$].

Intervention evaluation: Table 2 presents intervention evaluation data. Participants in both arms rated the

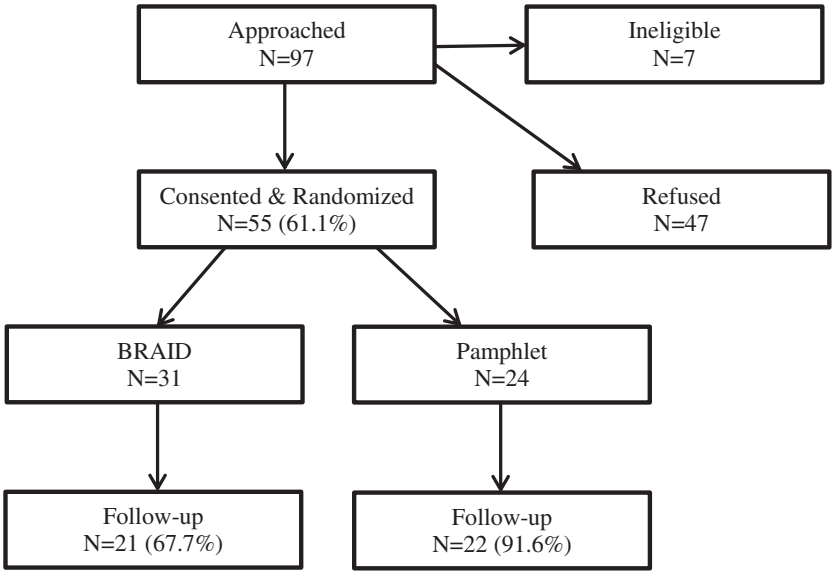

Figure 1. Consort diagram. BRAID, breast reconstruction decision support aid

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Table 2. Descriptive information on evaluations of the BRAID and pamphlet materials

	Study condition	
	BRAID (n = 21) M (SD)	**Pamphlet (n = 22) M (SD)**
Length of intervention	4.33 (0.80)	4.24 (0.77)
Presented in a balanced way	6.05 (1.28)	5.67 (1.35)
Helped with BR decision	6.05 (1.02)	4.57 (1.66)
Increased understanding of BR advantages/disadvantages*	6.09 (0.94)	5.01 (1.35)
Learn something new	6.38 (1.20)	5.70 (1.59)
Information was interesting*	6.33 (0.91)	5.52 (1.44)
Information was valuable	6.52 (0.75)	5.67 (1.43)
Information was easy to understand	6.47 (0.75)	6.00 (1.25)
Information was valid	6.52 (0.75)	5.95 (1.32)
Utilization	n (%)	n (%)
Viewed materials	16 (100)	21 (95.5)
Discussed with family/friends	18 (85.7)	9 (40.9)
Discussed with doctor	7 (33.3)	5 (22.7)
Overall use[a]*	2.19 (0.60)	1.59 (0.85)

BRAID, breast reconstruction decision support aid; SD, standard deviation; BR, breast reconstruction.

[a]Total of the three utilization items (range = 1–3), SDs of each outcome using observed data stratified by time point (baseline and follow up) and treatment arm (pamphlet and BRDA) along with p-values for change within treatment arm as well as comparison of changes across treatment arms (treatment effect).

*$p < 0.05$, significant difference between conditions.

materials favorably in th at the materials increased understanding of the advantages and disadvantages of BR, they learned something new, and the information was interesting, valuable, valid, and easy to understand; presented in a balanced way; and facilitated the BR decision. Eighty-one percent of BRAID participants found it easy to log in and easy to navigate. The length of the BRAID was rated as 'just right' by 81% of participants. As shown in Table 3, t-tests revealed that the BRAID was rated significantly more helpful than the pamphlet in that BRAID participants reported the aid helped them significantly more with the BR decision, the aid was more interesting and valuable, and the aid increased their understanding of the advantages and disadvantages of BR as compared with the pamphlet.

Intervention outcomes analyses

Results are shown in Table 3. BR knowledge, satisfaction with preparation, completeness of preparation and decisional conflict were significantly improved from baseline to follow-up within both treatment arms, and significant decreases in decisional conflict were found in both treatment arms. Increases in BR knowledge were 31.4% for the BRAID group and 32.3% for the pamphlet group. Increases in completeness of preparation, on a 4-point scale, were 1.41 in the BRAID group and 0.79 for the pamphlet group. Increases in satisfaction with preparation, on a 5-point scale, were 0.82 points for the BRAID group and 0.84 points for the pamphlet group. The largest change was seen in decisional conflict: Decreases of 13.2 points were found for BRAID group, and decreases of 16.2 points were found for the pamphlet group. Anxiety remained stable pre-intervention to post-intervention in both groups. With regard to secondary outcomes, reasons to have and not have BR remained unchanged. No differences were noted between groups. These results remained the same regardless of whether the observed data, multiple imputation, or last observation carried forward was used to account for missing data (Supplementary Information Tables 2 and 3).

In terms BR decisions, at follow-up, the same proportion of participants reported that they had decided to have BR in both groups, with 15.8% of BRAID participants deciding to have BR versus 12.2% of pamphlet participants

Table 3. Means (SDs) of each outcome using observed data stratified by time point (baseline and follow up) and treatment arm (pamphlet and BRDA) along with p-values for change within treatment arm as well as comparison of changes across treatment arms (treatment effect)

	Pamphlet			BRAID			p-value for treatment effect		
	Raw means (SD)			Raw means (SD)					
Outcome	**Baseline n = 24**	**Follow-up n = 22**	**p-value for change**	**Baseline n = 31**	**Follow-up n = 21**	**p-value for change**	**Observed data analysis**	**With multiple imputation**	**Last observation carried forward**
Knowledge about BR	0.344 (0.218)	0.667 (0.179)	<0.0001	0.336 (0.232)	0.650 (0.132)	<0.0001	0.91	0.94	0.40
Satisfaction with preparation	2.45 (1.01)[a]	3.29 (0.57)	0.0014	2.58 (0.89)[b]	3.40 (0.38)	0.0003	0.95	0.97	0.55
Completeness of preparation	2.61 (1.18)	3.40 (0.86)	0.014	2.53 (0.96)[c]	3.94 (0.57)	<0.0001	0.11	0.12	0.50
Decisional conflict	34.01 (28.7)	17.8 (17.1)	0.026	33.1 (20.3)	19.9 (12.5)	0.0096	0.73	0.73	0.41
Anxiety	43.3 (11.9)[a]	41.3 (9.7)[f]	0.57	47.5 (12.4)	48.0 (11.8)[e]	0.96	0.65	0.70	0.52
Reasons for having BR	3.46 (0.64)	3.20 (0.68)[e]	0.20	3.46 (0.62)[d]	3.51 (0.89)[e]	0.89	0.30	0.58	0.41
Reasons to not have BR	2.76 (0.56)	2.94 (0.50)	0.25	2.81 (0.50)	2.82 (0.53)	0.95	0.41	0.44	0.41

SD, standard deviation; BRDA,; BRAID, breast reconstruction decision support aid; BR, breast reconstruction.

[a]n = 23.

[b]n = 27.

[c]n = 28.

[d]n = 30.

[e]n = 20.

[f]n = 21.

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deciding to have BR [chi-square (1) = 0.11, n.s.]. Among the subset of participants at follow-up who reported not having made a firm decision, intentions to have BR declined in both groups, with no differences between groups.

Discussion

The goal of this study was to examine the acceptability and preliminary efficacy of a new web-based decision support aid, BRAID, which was designed to assist women considering mastectomy with the decision whether to pursue BR. The BRAID provides information about BR options, addresses specific patient attitudes and values about BR, and offers tailored feedback to help with the decision-making process. Results suggest that acceptability was relatively high: About 57% of women accepted participation in the study, 78% completed the follow-up survey, and 78% viewed some or all of the BRAID. About 85% of participants showed the website to their family and/or friends, and the majority of participants (85%) spent between more than 18 minutes viewing the website. The BRAID was highly rated in terms of ease of log in and navigation and length. In comparison with the Cancer Support Community's *Frankly Speaking About Cancer: Spotlight on Breast Reconstruction* pamphlet, the BRAID was rated as significantly more helpful to participants in making the BR decision and significantly more interesting and valuable and increased the patient's understanding of the advantages and disadvantages of BR. It is difficult to compare the acceptability with the three published studies, because the study design and measures differed. Our study dropout rate at follow-up (23%) was lower than that of Heller and colleagues [27] (50%), but their rate was calculated after randomization not at the time of the follow-up survey. The uptake or use of BRAID was similar to Heller and colleagues [27], in that the decision support aid was viewed by the majority of the participants and was evaluated more highly than the comparison group. Evaluations of the usefulness of the BRAID (M = 6.0–6.5 on a 7-point scale) were similar to Sherman and colleagues [36] (M = 3.1 to 4.1 on a 5-point scale). Because Lee and colleagues [28] did not collect evaluations of the decision support aid and did not employ a pre-post test design, comparisons cannot be made with this study.

Despite its satisfactory acceptability and positive evaluation, when we compared BRAID with a the *Frankly Speaking* pamphlet, which is widely available and free, the BRAID's impact on BR knowledge, decisional preparedness, and decisional conflict was similar to the pamphlet's impact. Significant improvements in BR knowledge and preparedness and significant reductions in decisional conflict were found in both treatment arms. Additionally, a similar proportion of participants reported that they had decided to have BR in both study groups. Among the subset of participants at follow-up who reported not having made a firm decision, intentions to have BR declined in both intervention arms, with no differences between groups. These findings suggest that those women who had not yet made a decision were likely to decide against BR, but there were no significant differences between groups. It is difficult to make comparisons with other BRAIDs because the control groups and outcomes in the other studies differed. For example, Lee and colleagues [28] developed an educational CD program about BR (computer-based learning) provided before surgical consultation and compared the educational program with a standard surgical consultation. They did not assess outcomes before the consultation. Results indicated that the computer-based learning group was more involved in decision-making, more satisfied with the amount of information provided, and able to recall the BR options, indicating superiority of the intervention. One of their outcomes overlapped with the present study (satisfaction with the amount of information), but their control group did not receive any print or additional information. Heller and colleagues [27] compared an educational interactive decision support aid that included illustrations, testimonials, and videotaped explanations from plastic surgeons about BR option standard care (print materials and surgical consult). Results indicated superiority of the decision support aid over standard care with regard to BR knowledge. However, none of these studies compared the intervention with a comprehensive print intervention.

Before concluding, study limitations should be considered. First, the sample size was small. Second, we did not evaluate possible moderators of treatment effects. For example, prior work has indicated that decision support aids provide more benefit for persons who exhibit more decision certainty [37]. Patients who were unsure about whether to pursue BR at baseline may have benefitted more from the BRAID than the pamphlet. An exploratory analysis indicated that satisfaction and completeness of preparation at the follow-up were significantly lower among BRAID participants who had not yet made a decision at baseline than among pamphlet participants. Unfortunately, the sample size was too small to formally evaluate moderation. Future larger scale studies may be able to evaluate this possibility. Third, although we attempted to recruit women >65 years of age and minority women (the patient population less likely to be offered BR), the majority were <60 years of age and White (75%). Fourth, although the majority had not yet had a consultation with a plastic surgeon at the baseline assessment time point, a small proportion (11%) had already consulted with a reconstructive surgeon. Fifth, we did not assess whether participants in the BRAID arm located and read the *Frankly Speaking* pamphlet. Sixth, we did not assess long-term outcomes such as satisfaction with the BR decision and with the type of reconstructive

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surgery. Seventh, feedback on the content and usability of BRAID during its development was provided by a small number of women, and there was no feedback about the BRAID from women not selecting BR. Eighth, the return rate at follow-up was lower in the BRAID arm than the pamphlet arm. Because of this fact, we do not know if women who did not complete the follow-up survey did not view the BRAID or did not find it useful. Finally, it would have been interesting to learn more about participants' views on the study in terms of their views on randomization.

Despite these limitations, our findings suggest that both a free pamphlet and a customized web-based decision support aid were associated with positive changes on a variety of decision-making and knowledge outcomes. Surgeons working with women considering mastectomy should consider using the Cancer Support Community's *Frankly Speaking* pamphlet because it improves BR knowledge and facilitates informed decisions about BR surgery.

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Conflict of interest

The authors have declared no conflicts of interest.

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